

REMARKS

By this Amendment, claims 3-7, 9, 10, 12, 19 and 20 have been amended, claims 1, 2, 8, 11 and 13-18 have been canceled, and new claims 21 and 22 have been added to the application. Accordingly, claims 3-7, 9, 10, 12, and 19-22 are pending in the application. No new matter has been added.

In the prior Office Action, the Examiner acknowledged applicant's election to prosecute the Group I invention. By this Amendment, claims directed to the non-elected subject matter have been cancelled.

Also in the prior Office Action, the Examiner rejected claims 2, 3 and 11 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner noted that claims 2 and 11 contained the phrase "(as defined herein)". By this Amendment, claims 2 and 11 have been cancelled thereby rendering the prior rejection thereof moot. Claim 3 was rejected as being indefinite for reciting a range within a range. By this Amendment, claim 3 has been amended to specify a single range. In view of the amendments to claim 3, reconsideration of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

The Examiner rejected claims 4, 5, 7-9, 12 and 19-20 under 35 U.S.C. §102(b) in the prior Office Action as being anticipated by Kang et al., *Journal of Applied Toxicology*, Vol. 12(6) (1992), pp. 443-449. With respect to Kang et al., the Examiner states that:

Kang discloses a condom comprising a finishing powder which comprises a particulate, substantially water-insoluble (since magnesium carbonate is insoluble in water), inorganic compound having substantially spherical particle morphology (see Table 1), wherein the finishing powder is magnesium carbonate (Table 1) which has a water solubility of less than 0.05 g per 100 g of water (since magnesium carbonate is not soluble in water).

Applicant respectfully submits that Kang et al. clearly does not anticipate the claims as amended herein. Kang et al. discloses the results of a study regarding the pathological effects of dusting powders used in the manufacture of latex gloves and condoms. As noted in the first line of Kang et al., dusting powders are used to facilitate

the release of latex gloves and condoms from their molds during the manufacturing process and to facilitate the processing and donning of such products. Several dusting powders were tested by Kang et al., including: silica; mica; talcum; lycopodium; calcium carbonate; magnesium carbonate; and Biosorb® starch. Kang et al. concluded that "Biosorb® starch is the least harmful of the dusting powders available for use on condoms." (see Kang et al., p. 448, col. 2, last paragraph).

It is the Examiner's contention that the magnesium carbonate mentioned in Kang et al. as a dusting powder for condoms is substantially spherical. This is not the case. Kang et al. characterize the magnesium carbonate particles as being "rough rounded granules" (see Table 1). The specification of the present application (see p. 5, lines 8-18 and Fig. 2) provides more information regarding the circularity of magnesium carbonates. Such materials do not possess good sphericity. The average circularity factor for standard magnesium carbonate is 16.7 (see specification at p. 6, lines 3-6).

Claim 12, as amended herein, claims:

A condom comprising a finishing powder which comprises a particulate, substantially water-insoluble, inorganic compound having an average circularity factor of 15 or below, wherein the circularity factor for each particle used to generate the average is measured according to the formula:

$$\text{circularity factor} = p^2/A$$

where p is the perimeter of a 2-D image of the particle and A is the area of the 2-D image of the particle.

The magnesium carbonate mentioned as a dusting powder in Kang et al. thus clearly does not meet the average circularity factor definition set forth in the specification at p. 5, lines 20-25, and now recited in claim 12. Accordingly, Kang et al. does not anticipate claim 12. Claims 4, 5, 7, 9, 12, 19 and 20 depend from claim 12, either directly or through an intervening claim, and are thus also not anticipated by Kang et al.

Also in the prior Office Action, the Examiner rejected claims 2, 3 and 11 under 35 U.S.C. §103(a) as being unpatentable over Kang et al. Applicant notes that claims 2

and 11 have been canceled, thereby rendering the prior rejection thereof moot. Applicant further notes that the average circularity factor of 15 or below limitation previously set forth in claim 3 is now incorporated in claim 12. The Examiner contends that:

Kang fails to disclose applicant's recited ranges for circularity factor. However, finding the optimum range for circularity is obvious and well within the level of one of ordinary skill in the art since finding the workable or optimal range for a result effective variable is obvious (MPEP 2144). Furthermore, it is an expected result that lowering the circularity factor improves processability since rounder particles result in lower friction.

As noted above, Kang et al. discloses the results of a study regarding the pathological effects of dusting powders used in the manufacture of latex gloves and condoms. The dusting powders studied by Kang et al. had a wide range of particle morphologies: silica - crystalline particles with irregular outlines; mica - irregular crystalline plates; talcum - irregular crystalline plates; lycopodium - rough rounded granules; calcium carbonate - single cuboid crystals and aggregates; magnesium carbonate - rough rounded granules; and Biosorb[®] starch - smooth rounded granules (see Table 1). There is no teaching in Kang et al. that one particle morphology is better than another. And thus, there is nothing in Kang et al. that would lead one of ordinary skill in the art to modify the morphology of the particles for any reason. The general teaching of Kang et al. is that the particle morphologies disclosed therein are quite satisfactory for use as dusting powders, so one having ordinary skill in the art would simply follow this teaching.

The phrase dusting powders has been underlined throughout because dusting powders are quite different than the finishing powders referenced in claim 12. As noted by Kang et al., dusting powders help control the surface tack of products, for example to facilitate the release of products from their molds. Dusting powders do not perform a lubricating function. Dusting powders are used primarily to overcome the inherent adhesion between latex films and the surface of the mold or former on which the latex films are made, and to overcome the inherent tackiness of the latex from which the

article is made, rather than to reduce friction by providing lubrication, as is the case for finishing powders.

There is no teaching in Kang et al. that the morphology of the particles (used in dusting powders) is of any importance whatsoever. In fact, Kang et al. specifically teaches on p. 446, second column, last paragraph, that:

no consensus exists regarding the choice of dusting agent to use on condoms or other products, such as diaphragms, toiletries or sanitary napkins. At present, the choice of dusting agent is determined by factors such as the availability of a suitable agent, the manufacturing convenience of such a powder and its acceptability to the user.

Thus, one having ordinary skill in the art would not be motivated by the teachings of Kang et al. to modify the morphology of a finishing powder for any reason at all, and would not have any motivation to find a particles having any particular average circularity factor. There simply is not teaching on this subject.

The present invention addresses the problem of conventional condom finishing powders (which comprise irregular particles) being ineffective in reducing friction and giving problems during condom rolling and unrolling, and impeding lubricant migration, resulting in condoms that are difficult to roll and use. This problem is not identified in Kang et al. Kang et al. does not point towards the problems of friction and impedance of lubricant migration, which the present applicant has now realized are associated with conventional condom finishing powders. Furthermore, Kang et al. does not point towards any solution to these problems. In the absence of any recognition of the problems associated with spicular particles, one having ordinary skill in the art would not have seen any need to modify the teaching of Kang et al. for any reason. And thus, it would not have been obvious to one having ordinary skill in the art to use particles having a circularity factor of 15 or below as now claimed in claim 12, or to use particles having a circularity factor of 14 or below as now claimed in claim 3. Reconsideration of the rejections set forth under 35 U.S.C. §103(a) is thus respectfully requested.

Finally, in the prior Office Action the Examiner objected to claim 6 as being dependent upon a rejected base claim, but indicated that claim 6 would be allowable if

rewritten in independent form including all of the limitations of the base claim and any intervening claims. By this Amendment, claim 6 has been rewritten in independent form including all of the limitations of the base claim and intervening claims. Claim 6 is thus deemed to be in condition for allowance.

In light of the foregoing, it is respectfully submitted that the present application is in condition for allowance and a notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge the same to Deposit Account No. 18-0160, Order No. AAT-15784.

Respectfully submitted,

RANKIN, HILL, PORTER & CLARK LLP

By: /Randolph E. Digges, III/

Randolph E. Digges, III
Reg. No. 40590

700 Huntington Building
925 Euclid Avenue
Cleveland, Ohio 44115-1405
TEL: (216) 566-9700
FAX: (216) 566-9711
docketing@rankinhill.com